

RULE ANALYSIS

Introduction: THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS ADOPTED RULE

Short Title: Labeling

Rule Numbers: §291.125

Statutory Authority: Texas Pharmacy Act, Chapter 551-566 and 568-569, Occupations Code:

- (1) Section 551.002 specifies that the purpose of the Act is to protect the public through the effective control and regulation of the practice of pharmacy; and
- (2) Section 554.051 gives the Board the authority to adopt rules for the proper administration and enforcement of the Act.

Purpose: The amendments, if adopted, add definitions of central fill pharmacy and outsourcing pharmacy; and allow the central fill pharmacy to be identified on the prescription label by a unique identifier.

The Board reviewed and voted to propose the amendments during the November 5, 2013, meeting. The proposed amendments were published in the December 13, 2013, issue of the *Texas Register* at 38 TexReg 9000.

1 **SUBCHAPTER G. SERVICES PROVIDED BY PHARMACIES**

2 **22 TAC §291.125**

3 The Texas State Board of Pharmacy proposes amendments to §291.125, concerning Centralized
4 Prescription Dispensing. The proposed amendments to §291.125, if adopted, add definitions of
5 central fill pharmacy and outsourcing pharmacy; and allow the central fill pharmacy to be
6 identified on the prescription label by a unique identifier.

7 Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year
8 period the amended rule is in effect, there will be no fiscal implications for state or local
9 government as a result of enforcing or administering the amended rule.

10 Ms. Dodson has determined that, for each year of the first five-year period the amended rule will
11 be in effect, the public benefit anticipated as a result of enforcing the amendments will be to
12 identify the central filling pharmacy by a unique identifier. There is no fiscal impact for
13 individuals, small or large businesses, or to other entities which are required to comply with the
14 amended rule.

15 Written comments on the amendments may be submitted to Allison Benz, R.Ph., M.S., Director
16 of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600,
17 Austin, Texas 78701, FAX (512) 305-8008. Comments must be received by 5:00 p.m., January
18 24, 2014.

19 The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act
20 (Chapters 551 - 566, 568 and 569, Texas Occupations Code). The Board interprets §551.002 as
21 authorizing the agency to protect the public through the effective control and regulation of the
22 practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules
23 for the proper administration and enforcement of the Act.

24 The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 566, 568 and
25 569, Texas Occupations Code.

26 **§291.125. Centralized Prescription Dispensing.**

27 (a) Purpose. The purpose of this section is to provide standards for centralized prescription
28 dispensing by a Class A (Community), Class C (Institutional) pharmacy, or Class E (Non-
29 Resident) Pharmacy.

30 (b) Definitions. The following words and terms, when used in this section, shall have the
31 following meanings, unless the context clearly indicates otherwise. Any term not defined in this
32 section shall have the definition set out in the Act.

33 (1) Central fill pharmacy--a Class A, Class A-S, Class C, Class C-S, Class E, or Class E-S
34 pharmacy that prepares prescription drug orders for dispensing pursuant to a valid prescription
35 transmitted to the central fill pharmacy by an outsourcing pharmacy.

36 (2) Centralized prescription dispensing--the dispensing or refilling of a prescription drug order
37 by a Class A [~~(Community)~~], Class C [~~(Institutional)~~], or Class E [~~(Non-Resident)~~] pharmacy at
38 the request of another Class A [~~(Community)~~], or Class C pharmacy [~~(Institutional)~~]- and the
39 return of the dispensed prescriptions to the outsourcing [~~requesting~~] pharmacy for delivery to the
40 patient or patient's agent, or at the request of the outsourcing [~~requesting~~] pharmacy for direct
41 delivery to the patient.

42 (3) Outsourcing pharmacy--a Class A or Class C pharmacy that transmits a prescription drug
43 order to a central fill pharmacy to be dispensed by the central fill pharmacy.

44 (c) Operational standards.

45 (1) General requirements.

46 (A) A Class A [~~(Community)~~] or Class C [~~(Institutional)~~] pharmacy may outsource prescription
47 drug order dispensing to a central fill [~~other Class A (Community), Class C (Institutional), or~~
48 ~~Class E (Non-Resident)] pharmacy provided the pharmacies:~~

49 (i) have:

50 (I) the same owner; or

51 (II) entered into a written contract or agreement which outlines the services to be provided and
52 the responsibilities and accountabilities of each pharmacy in compliance with federal and state
53 laws and regulations; and

54 (ii) share a common electronic file or have appropriate technology to allow access to sufficient
55 information necessary or required to dispense or process a prescription drug order.

56 (B) The pharmacist-in-charge of the central fill [~~dispensing~~] pharmacy shall ensure that:

57 (i) the pharmacy maintains and uses adequate storage or shipment containers and shipping
58 processes to ensure drug stability and potency. Such shipping processes shall include the use of
59 appropriate packaging material and/or devices to ensure that the drug is maintained at an
60 appropriate temperature range to maintain the integrity of the medication throughout the delivery
61 process; and

62 (ii) the dispensed prescriptions are shipped in containers which are sealed in a manner as to show
63 evidence of opening or tampering.

64 (C) A Class A [~~(Community)~~] or Class C central fill [~~(Institutional) dispensing~~] pharmacy shall
65 comply with the provisions of §§291.31 - 291.35 of this title (relating to Definitions, Personnel,
66 Operational Standards, Records, and Official Prescription Requirements in Community
67 Pharmacy (Class A) [~~Class A (Community) Pharmacies~~]) and this section.

68 (D) A Class E central fill [~~(Non-Resident) dispensing~~] pharmacy shall comply with §§291.101 -
69 291.105 of this title (relating to Purpose, Definitions, Personnel, Operational Standards, and
70 Records in Non-resident Pharmacy (Class E) [~~Class E (Non-Resident) Pharmacies~~] and this
71 section.

72 [~~(E) Pharmacies dispensing compounded non-sterile or sterile preparations shall comply with the~~
73 ~~provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile~~
74 ~~Preparations) and §291.133 of this title (relating to Pharmacies Compounding Sterile~~
75 ~~Preparations).]~~

76 (2) Notifications to patients.

77 (A) A pharmacy that outsources prescription dispensing to a central fill [~~another~~] pharmacy
78 shall:

79 (i) prior to outsourcing the prescription:

80 (I) notify patients that their prescription may be outsourced to a central fill [~~another~~] pharmacy;
81 and

82 (II) give the name of the central fill [~~that~~] pharmacy or if the pharmacy is part of a network of
83 pharmacies under common ownership and any of the network pharmacies may dispense the
84 prescription, the patient shall be notified of this fact. Such notification may be provided through
85 a one-time written notice to the patient or through use of a sign in the pharmacy; and

86 (ii) if the prescription is delivered directly to the patient by the central fill [~~dispensing~~] pharmacy
87 and not returned to the outsourcing [~~requesting~~] pharmacy, place on the prescription container or
88 on a separate sheet delivered with the prescription container, in both English and Spanish, the
89 local, and if applicable, the toll-free telephone number of the pharmacy and the statement:
90 "Written information about this prescription has been provided for you. Please read this
91 information before you take the medication. If you have questions concerning this prescription, a
92 pharmacist is available during normal business hours to answer these questions at (insert the
93 pharmacy's local and toll-free telephone numbers)."

94 (B) The provisions of this paragraph do not apply to patients in facilities where drugs are
95 administered to patients by a person required to do so by the laws of the state (e.g., [~~i.e.,~~]
96 hospitals or nursing homes).

97 (3) Prescription Labeling. The central fill [~~dispensing~~] pharmacy shall[~~;~~] place on the
98 prescription label, the name and address of the outsourcing pharmacy and a unique identifier
99 (i.e., the central fill pharmacy's DEA registration number or, if the pharmacy does not have a
100 DEA registration number, the central fill pharmacy's Texas license number) indicating that the
101 prescription was dispensed by the central fill pharmacy; and comply with all other labeling
102 requirements in §291.33 of this title.

103 ~~{(A) place on the prescription label, the name and address or name and pharmacy license number~~
104 ~~of the pharmacy dispensing the prescription and the name and address of the pharmacy which~~
105 ~~receives the dispensed prescription;}~~

106 ~~{(B) indicate in some manner which pharmacy dispensed the prescription (e.g., "Filled by ABC~~
107 ~~Pharmacy for XYZ Pharmacy"); and}~~

108 ~~{(C) comply with all other labeling requirements in §291.33 of this title.}~~

109 (4) Policies and Procedures. A policy and procedure manual as it relates to centralized
110 dispensing shall be maintained at both pharmacies and be available for inspection. Each
111 pharmacy is required to maintain only those portions of the policy and procedure manual that
112 relate to that pharmacy's operations. The manual shall:

113 (A) outline the responsibilities of each of the pharmacies;

114 (B) include a list of the name, address, telephone numbers, and all license/registration numbers
115 of the pharmacies involved in centralized prescription dispensing; and

116 (C) include policies and procedures for:

117 (i) notifying patients that their prescription may be outsourced to a central fill pharmacy for
118 ~~[another pharmacy for centralized prescription]~~ dispensing and providing the name of that
119 pharmacy;

120 (ii) protecting the confidentiality and integrity of patient information;

121 (iii) dispensing prescription drug orders when the dispensed ~~[filled]~~ order is not received or the
122 patient comes in before the order is received;

123 (iv) complying with federal and state laws and regulations;

124 (v) operating a continuous quality improvement program for pharmacy services designed to
125 objectively and systematically monitor and evaluate the quality and appropriateness of patient
126 care, pursue opportunities to improve patient care, and resolve identified problems; and

127 (vi) annually reviewing the written policies and procedures and documenting such review.

128 (d) Records.

129 (1) Records may be maintained in an alternative data retention system, such as a data processing
130 system or direct imaging system provided:

131 (A) the records maintained in the alternative system contain all of the information required on
132 the manual record; and

133 (B) the data processing system is capable of producing a hard copy of the record upon the
134 request of the board, its representative, or other authorized local, state, or federal law
135 enforcement or regulatory agencies.

136 (2) Each pharmacy shall comply with all the laws and rules relating to the maintenance of
137 records and be able to produce an audit trail showing all prescriptions dispensed by the
138 pharmacy.

139 (3) The outsourcing [~~requesting~~] pharmacy shall maintain records which indicate the:

140 (A) date:

141 (i) [~~(A)~~] the request for dispensing was transmitted to the central fill [~~dispensing~~] pharmacy; and

142 (ii) [~~(B)~~] the dispensed prescription was received by the outsourcing [~~requesting~~] pharmacy,
143 including the method of delivery (e.g., private, common, or contract carrier) and the name of the
144 person accepting delivery; and[-]

145 (B) name, address, license number, and the unique identifier of the central fill pharmacy.

146 (4) The central fill [~~dispensing~~] pharmacy shall maintain records which indicate the:

147 (A) [~~the~~] date the prescription was shipped to the outsourcing [~~requesting~~] pharmacy or the
148 patient;

149 (B) [~~the~~] name and address where the prescription was shipped; [~~and~~]

150 (C) [~~the~~] method of delivery (e.g., private, common, or contract carrier); and[-]

151 (D) name, address, and license number of the outsourcing pharmacy.



January 17, 2014

Allison Benz, RPh, MS
Texas State Board of Pharmacy
William P. Hobby Building
333 Guadalupe Street, Suite 3-600
Austin, TX 78701-3942

RE: Comments to Proposed Rules for Adoption

Dear Ms. Benz:

On behalf of HEB, I appreciate the opportunity to submit comments regarding the proposed new rules under §291.125 (Services Provided By Pharmacies)

H-E-B currently operates 235 pharmacies in the state of Texas and employs over 700 pharmacists, 1400 registered pharmacy technicians and pharmacy technician trainees, and 400 non-registered individuals. Our pharmacies provide prescription services along with other healthcare services such as immunizations, medication therapy management, disease state management, and health screenings to the citizens of Texas.

§291.125 (Services Provided By Pharmacies) as it relates to Central Fill Pharmacies and "Outsourcing" Pharmacies

We support the Proposed Rule to modify the labeling requirements as it relates to Centralized Prescription Dispensing. By removing the constraint that each address of the pharmacies involved must be printed on the prescription label and the provision of a unique identifier for the Central Fill facility (i.e. DEA number), this will mitigate confusion on the part of the consumer as to where the prescription resides. The patient will contact the appropriate outsourcing pharmacy if questions or concerns arise. In addition, there will be no effect on accountability or responsibility of the outsourcing pharmacy.

Thank you for consideration of our comments.

Please do not hesitate to contact me with any questions, concerns, or further assistance.

Respectfully,

A handwritten signature in black ink, appearing to read 'Doug Read', with a stylized flourish at the end.

Doug Read, Pharm.D.
Director of Pharmacy Compliance and Regulatory Affairs
H-E-B Pharmacy
3481 Fredericksburg Rd, Suite #2
San Antonio, TX 78201



December 25, 2013

Allison Benz, R.Ph., M.S.
Director of Professional Services
Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-600
Austin, Texas 78701

Re: Proposed Rule 22 TAC §291.125 Centralized Prescription Dispensing

Dear Ms. Benz:

As a leading pharmacy health care provider in the United States, CVS Caremark appreciates the opportunity to submit comments for your consideration in support of Texas State Board of Pharmacy Proposed Rule 22 TAC §291.125 Centralized Prescription Dispensing.

CVS Caremark applauds the efforts of the Texas State Board of Pharmacy to decrease patient confusion while maintaining pharmacy accountability by amending the prescription labeling requirement under 22 TAC §291.125(c)(3). The amended language, as follows, provides consistency with Federal DEA requirements, as well as other State labeling requirements.

Prescription Labeling. The central fill pharmacy shall place on the prescription label, the name and address of the outsourcing pharmacy and a unique identifier (i.e., the central fill pharmacy's DEA registration number or, if the pharmacy does not have a DEA registration number, the central fill pharmacy's Texas license number) indicating that the prescription was dispensed by the central fill pharmacy; and comply with all other labeling requirements in §291.33 of this title.

We believe that this positive change will allow pharmacies the flexibility to engage in the practice models that best serve their patients, while at the same time minimizing any confusion that patients may have when contacting their pharmacy providers. The notice and record requirements of the rule maintain the ability of the Board to track and hold accountable each pharmacy involved in the process if a negative event were to occur.

CVS Caremark appreciates the opportunity to submit comments for the proposed regulation. If you have any questions, please contact Brian Files, Director of Policy, at 202.772.3500.

Sincerely,

A handwritten signature in black ink, appearing to read "Allen K. Horne", written over a white background.

Allen K. Horne
Vice President, Government Affairs